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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,361	08/21/2003	Xian-Ming Zeng	TEVE-121US	8629

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EXAMINER	
BROOKS, KRISTIE LATRICE	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/646,361	ZENG, XIAN-MING	
	Examiner	Art Unit	
	KRISTIE L. BROOKS	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/18/09; 7/17/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on December 18, 2009 has been entered.

New Ground of Rejection

Status of Application

2. Claims 1-15 are pending.

3. New Examiner of Record. Kristie L. Brooks. Art Unit 1616.

4. Receipt and consideration of Applicants amendments/remarks filed on December 18, 2009 is acknowledged.

5. Rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al. (US 6,645,466) in view of Ward et al. (US 6,616,914).

Application Claims

A dry powder inhalation composition comprising, (a) medicament particles, and (b) a mixture of lactose particles with a VMD of between about 70 and about 120 microns and a diameter of less than 250 microns, wherein up to 96% by weight of the lactose particles are less than 150 microns in diameter and wherein up to 25% by weight of the lactose particles are less than 5 microns in diameter.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Keller et al. teach dry powder formulations for inhalation and delivery to the lung comprising a pharmaceutically ineffective carrier of not-inhalable size and a finely divided pharmaceutically active compound of inhalable particle size (see the abstract, column 1, lines 16-21, and the Examines). The pharmaceutically active compound of an inhalable size has a mean mass aerodynamic diameter (MMAD) of at most 10 µm (see column 4, lines 56-67 and column 6, lines 2-7). The particles can be prepared by spray-drying or micronization (see column 6, lines 7- 12). Examples of pharmaceutical actives include formoterol, fenoterol, etc. (see column 6, lines 13-37). One or more actives may be used see column 6 lines 35-37). The actives are present in an amount of 0.1 to 10% by weight of the formulation (see column 7 lines 11-21). The non-inhalable coarse carrier particles have a mean mass aerodynamic diameter (MMAD) of about 10 to 500 µm (see column 7, lines 40-53). The formulation can also contain a proportion of inhalable carrier particles having a particle size diameter (as (MMAD) of at most 10 µm and are present in the formulation in an amount of 0.1 to about 10% by weight (see column 8, lines 8-16, and claims 1-6). The carrier material may be present in a total amount of 80 to 99.9% by weight (see column, 8 lines 22-25). Examples of the carrier include lactose (see column 5, lines 58-65 and column 8, lines 1-9). The optimum particle size of the carrier depends on the demands and specifications of the powder inhaler intended for administration of the formulation (see column 7, lines 40-53).

Examples 1-6 teach lactose monohydrate having a broad range of particle size distribution.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Keller et al. teach a dry formulation composition comprising a mixture of lactose particles having a large particle size ranging preferably from 50 to 200 microns and a fine particle size of at most 10 microns but do not specifically teach the carrier particles having a volume median diameter ranging between 70 and 120 microns. This deficiency is cured by the teachings of Ward et al.

Ward teaches a method for oral and pulmonary delivery of pharmaceuticals, wherein a powder formulation for use in a dry powder inhaler (DPI) comprises a pharmaceutical, which acts as its own carrier and is present as (a) microfine particles having an average volume median diameter in the range of 1-10 microns and larger carrier particles that have an average volume median diameter of 10-2,000 microns, preferably 30-300 microns, and most preferably from 50-100 microns in diameter, and administration of the composition results in both a rapid onset pharmaceutical effect and a slower onset pharmaceutical effect (see abstract, column 2, lines 20-25 and 51-56, and claims 1-23). Ward teaches that suitable medicaments for use in the invented formulations include beta-agonists (i.e. a known class of bronchodilators), such as

albuterol, anti- inflammatories, and drugs for treating COPD and other diseases (see column 4, lines 21-28). Ward teaches that the invented composition is desirable to improve patient compliance for patients taking more than one pharmaceutical (see column 1, line 60 through column 2, line 13) and that, in general, inert carrier particles such as lactose upon inhalation administration are caught in the mouth and throat, swallowed, and exert no pharmaceutical effect (column 3, lines 5-12).

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

One of ordinary skill in the art would have been motivated to make a dry powder formulation comprising lactose particles having a volume median diameter ranging between 70 and 120 microns because it is known in the art that dry powder inhalation formulations comprising lactose carrier particles having a volume median diameter ranging from preferably about 30 to 300 microns can deliver active compounds to the lungs with a fasting acting or rapid onset of effect, as suggested by Ward et al.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a dry powder formulation with lactose particles having a volume median diameter (VMD) ranging between 70 and 120 microns because it is an obvious VMD range that can be used in the preparation of dry powder formulations for delivery of an active to the lungs.

It is noted that Ward et al. do not teach up to 96% by weight of lactose particles having a particles size less than 150 microns or up to 25% by weight of lactose particles having a particles size less than 5 microns. However, Keller et al. do suggest that 10% of the carrier particles can have a particle size of at most 10 microns (see column 8 lines 9-16). Keller et al. also teach formulations comprising lactose of various particle sizes and suggest that the optimum particle size of the carrier depends on the demands and specifications of the powder inhaler intended for administration of the formulation (see column 7, lines 40-53 and the Examples). Absent a clear showing of criticality of the percentages as claimed, the determination of particular concentrations is within the boundaries of routine experimentation of one skilled in the art as part of the process of normal optimization to achieve the desired dry powder formulation.

With respect to claim 15, "wherein said portion of coarse lactose particles is prepared by a method comprising collecting lactose particles on a mesh with mesh size of 63 microns after passing through a mesh with mesh size of 90 microns" it is noted that Keller et al. do not specifically teach the instantly claimed method of preparation. However, the patentability of a product does not depend on its method of production. If the product in the product- by-process claims is the same or obvious from a product in the prior art, the claim will be held unpatentable even if the prior product is made by a different process (See MPEP 2113).

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made because the prior art is fairly suggestive of the claimed invention.

Response to Arguments

Applicant's arguments with respect to claims 1-15 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristie L. Brooks whose telephone number is (571) 272-9072. The examiner can normally be reached on M-F 8:30am-6:00pm Est. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kristie L Brooks

Examiner, Art Unit 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616